



Testimony
Before the Committee on Government Reform
U.S. House of Representatives

**Working Through an Outbreak: Pandemic Flu
Planning and Continuity of Operations**

Statement of

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For Release on Delivery
Expected at 10:00 a.m.
Wednesday, May 11, 2006

Mr. Chairman and members of the Committee, I am honored to be here today to describe for you how the Department of Health and Human Services (HHS) is working to improve the nation's preparedness for a potential human influenza pandemic. Thank you for the invitation to testify on this issue, which is one of our highest priorities at HHS.

Strategy and Threat Assessment

On November 1, 2005, President Bush released the *National Strategy for Pandemic Influenza*, which outlines the roles of the Federal government and sets expectations for State, local, and tribal governments, private and international partners, and individual citizens in preparing for and responding to an influenza pandemic. The following day, Secretary Leavitt announced the *HHS Pandemic Influenza Plan*-a blueprint for all HHS pandemic influenza preparedness and response planning. The HHS Plan provides guidance to national, State, and local policy makers and health departments with the goal of achieving national readiness and the ability to respond quickly and effectively to a pandemic. The HHS plan also includes an outline of key HHS roles and responsibilities during a pandemic. In the event of a pandemic, under the National Response Plan, HHS will lead the public health and medical response with the Department of Homeland Security carrying out its responsibility for overall domestic incident management and Federal coordination. However, ultimately, the center of gravity for such a response will be at the state and local level.

As you know, the President requested \$7.1 billion in emergency funding for the *National Strategy for Pandemic Influenza*, of which \$6.7 billion was requested for HHS. Congress appropriated \$3.8 billion as the first installment of the President's request to begin these priority activities, and of this amount, \$3.3 billion was provided to HHS. We appreciate the action of Congress on this appropriation as it takes us an essential step forward to becoming the first generation in history to be prepared for a possible pandemic.

We must also continue to prepare against a possible pandemic influenza outbreak. The President's Budget includes \$2.3 billion in funding for the 2007 portion of the emergency funding request to fulfill the next phase of the Strategy. It is vital that this funding be allocated in the most effective manner possible to achieve our preparedness goals, including producing pandemic influenza vaccine for every American within six months of detection of sustained human-to-human transmission of bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, state and local as well as international public health infrastructure and preparedness.

The President's FY 2007 budget also requests more than \$350 million for important ongoing pandemic influenza activities at HHS such as safeguarding the Nation's food supply (FDA), global disease surveillance (CDC), and accelerating the development of vaccines, drugs, and diagnostics (NIH).

Pandemics are not new. There were three in the 20th century, the worst of which was the Spanish flu epidemic in 1918-1919 that is estimated to have killed over one half million people in the U.S. and 50 million worldwide. While we are focusing today on the impact

of the H5N1 avian flu virus from a strain currently circulating in birds in many parts of Asia and Europe, many of the policy issues and preparedness measures that arise for this strain of influenza apply as well to pandemics of other types of influenza, other emerging infectious disease outbreaks and public health emergencies. For example, pandemic preparedness offers tangible benefits in the fight against seasonal influenza which causes an average of 36,000 deaths each year.

Scientists cannot accurately predict the severity and impact of an influenza pandemic, whether from the H5N1 virus or the emergence of another influenza virus of pandemic potential. However, it is still useful to model possible scenarios based on analysis of past pandemics. In a report released in December 2005, the Congressional Budget Office presented the results of modeling a severe pandemic scenario similar to the 1918 Spanish flu outbreak and a more moderate outbreak resembling the flu pandemics of 1957 and 1968. In the severe scenario, roughly 90 million people become ill and 2 million die in the United States and the impact on the real Gross Domestic Product [GDP] is about a 5 percent reduction in the year following the outbreak. While there is substantial uncertainty associated with these estimates, they illustrate the enormous public health threat of an influenza pandemic and the need for effective access to vaccines, treatments, and a robust public health infrastructure to meet the challenge.

There are several important points to note about an influenza pandemic:

- A pandemic could occur anytime during the year and is unlikely to behave like a typical seasonal influenza. Rather, past pandemics have occurred in multiple "waves" of infection and could persist in the world for over a year.

- In the absence of effective vaccines and antivirals, the capacity to prevent or control transmission of the virus once it gains the ability to be efficiently transmitted from person to person will be limited.
- Right now, the H5N1 avian influenza strain that is circulating in Asia and Europe among birds is a significant concern, but there is no way to know whether this virus will in fact lead to a human pandemic. Whether or not the H5N1 adapts itself to the human host, we know that influenza viruses are constantly evolving, and it is possible that this strain or another influenza virus, which could originate anywhere in the world, could cause the next pandemic. This uncertainty is one of the reasons why we need to maintain year-round surveillance of influenza viruses to be able to determine if there are genetic changes that may signal a potential pandemic, to develop reference viruses that can be used to develop pandemic vaccines, and to assess whether influenza viruses have developed resistance to antiviral drugs. As is the case with the H5N1 that is currently in birds around the world, pandemic influenza viruses often emerge in animals. Like other viruses, they tend to remain within a species. However, as we have seen already in the more than 200 documented cases of human infection of H5N1 confirmed by the World Health Organization, they do have the ability to infect humans who have been exposed to infected birds. Of greatest concern for human health is the question of whether the viruses will develop the ability to readily infect people and whether these viruses will be able to transmit efficiently from person to

person as is the case with seasonal flu. For all of these reasons, it is critical to maintain constant surveillance of viruses worldwide affecting animal populations and that can potentially be transmitted to humans.

- We often look to history in an effort to understand the impact that a new pandemic might have, and how to intervene most effectively. However, there have been many changes in society since the "great influenza" of 1918, including dramatic changes in population and social structures, medical and technological advances, and a significant increase in international travel. Some of these changes have increased our ability to plan for and respond to pandemics, but other changes may have made us more vulnerable.

HHS Preparations for Pandemic Influenza

As you know, the President announced the *Implementation Plan for the National Strategy for Pandemic Influenza* on May 3, 2006. The purpose of this plan is to ensure that the efforts and resources of the Federal government and State, local and tribal governments and the private sector will be brought to bear in a coordinated manner against the pandemic threat. The *Plan* describes more than 300 critical actions, many of which have already been initiated, to address the threat of pandemic influenza. The *Implementation Plan for the National Strategy for Pandemic Influenza* confirms HHS' role as the lead federal agency for the public health and medical preparation and planning for and response to a pandemic. The Secretary of HHS will lead the Federal health and medical

response efforts, serve as the primary Federal spokesperson for pandemic health issues, and coordinate the actions of other departments and agencies in the overall public health and medical emergency response efforts. The Secretary of the Department of Homeland Security (DHS) will provide broader overall incident management for the Federal response, will ensure necessary support to HHS to coordinate the public health response, and coordinate with HHS and other Federal, State, and tribal agencies in providing non-medical support.

The timing of the release of this Plan does not signal that a pandemic is imminent. The Plan is the result of much work in many Federal Departments and agencies to further prepare the government for a pandemic, whenever it might occur. It is important to note that the H5N1 avian influenza is a disease of birds, the virus has not yet appeared in the U.S., and there is no influenza pandemic in the world at this time.

HHS has been working with many Federal agencies, including the U.S. Department of Agriculture, the Departments of Homeland Security, State and others, in drafting the public health and medical aspects of the *Implementation Plan for the National Strategy*. The Plan spells out over 199 specific tasks that HHS will take the lead in or play a supporting role in to accomplish the human health aspects of the strategy. It is important to note that HHS has already started to make progress on many of the tasks delineated in the plan.

The Department's key tasks outlined in the plan include:

- Building stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat;
- Expanding domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire U.S. population within 6 months of a pandemic declaration;
- Building stockpiles of antivirals adequate to treat 25% of the U.S. population, divided between Federal and State stockpiles;
- Building a Federal stockpile of 6 million treatment courses reserved for domestic containment efforts.
- Developing clear guidelines and decision criteria to assist State, local, and tribal governments and the private sector in defining groups that should receive priority access to existing limited supplies of vaccine and antiviral medications and other critical medical care.
- Working with State and tribal entities to develop and exercise influenza countermeasure distribution plans and to include the necessary logistical support of such plans, including security provisions.

- Establishing a strategy for deploying Federal medical providers from across the USG, including expanding and enhancing programs such as the Medical Reserve Corps and supporting the transformation of the Commissioned Corps of the Public Health Service.
- Creating plans to rapidly credential, organize, and incorporate volunteer health and medical providers as part of the medical response in areas that are facing workforce shortages.
- Supporting local and national efforts to:
 - establish “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories;
 - link hospital and acute care health information systems with local public health departments; and
 - advance the development of the analytical tools necessary to interpret and act upon these data streams in real time.
- Establishing a single interagency hub for infectious disease modeling efforts, and ensuring that this effort integrates related modeling efforts for transportation decisions, border interventions, economic impact, etc. HHS will also work to ensure that this modeling can be used in real time as information about the characteristics of a pandemic virus and its impact become available.

- Providing guidance to all levels of government on a range of options for infection control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.

Current HHS Progress

In December 2005, Congress appropriated \$3.8 billion to help the Nation prepare for pandemic influenza preparedness activities. Of that total, Congress allocated \$3.3 billion to HHS for the first year of funding of the HHS Pandemic Influenza Plan. HHS will use these emergency funds to help achieve five primary objectives:

1. Monitoring disease spread to support rapid response;
2. Developing vaccines and vaccine production capacity;
3. Stockpiling antivirals and other countermeasures;
4. Coordinating Federal, State and local preparation; and
5. Enhancing outreach and communications planning.

HHS is working both domestically and internationally to monitor the spread of H5N1 and other possible pandemic viruses. On the international front, HHS is spending \$125 million of its FY 06 allowance to promote international pandemic preparedness and planning and augment existing capabilities in areas such as international surveillance,

epidemiological investigation, and diagnosis of illness. Through collaborations with the World Health Organization (WHO), the United Nations Food and Agriculture Organization, the World Organization for Animal Health, and numerous national governments, HHS is working to build capacity in other countries to detect outbreaks early and to contain the spread of the virus. HHS has signed Memoranda of Understanding (MOUs) on influenza and other emerging infectious diseases with Institute Pasteur (IP); the Gorgas Institute and the Ministry of Health of Panama; and most recently, the International Center for Diarrheal Disease Research, Bangladesh (ICDDR,B). HHS experts have participated in WHO-led investigations into human cases of avian influenza in Indonesia, China, and Turkey and are providing substantial technical assistance for influenza containment activities to many other countries on an as needed basis. Overall, HHS is supporting influenza activities in approximately 40 countries and has assigned influenza staff to the World Health Organization (WHO) Secretariat, Regional, and country offices in Europe and Southeast Asia.

On the domestic front, CDC is devoting \$50 million to strengthen local laboratory capacity and capability and \$35 million to accelerate the implementation of the national BioSense program to enhance our ability to detect an outbreak early. On January 1, 2006, BioSense RT (Real-Time) was launched in 10 select cities and 32 healthcare institutions across the country. Real-time transmission of existing clinical diagnostic and health information is being sent to CDC and analyzed. In April 2006, CDC launched a new data visualization and analysis tool for the use of all jurisdictional levels of public health (hospital, city, county, state, national). The BioSense implementation timeline is to link up to several hundred hospitals in over 30 cities by the end of 2006.

In the event of a pandemic, infection control practices and social distancing measures (such as school closures, cancellation of public gatherings, etc), and antiviral drugs will be the first line of defense before a vaccine is available and could limit and delay the spread of the pandemic. Currently, the Strategic National Stockpile (SNS) has over 5 million treatment courses of antiviral drugs on hand. On March 22, Secretary Leavitt announced the purchase of additional antiviral drugs that could be used in the event of a potential influenza pandemic. With these purchases, the SNS will have 26 million treatment courses of antiviral drugs that will be available to the States when an influenza pandemic is imminent. HHS' strategy is to federally procure an additional 24 million treatment courses of antiviral drugs through FY 07 and FY 08 funds and to offer a 25 percent federal subsidy for state purchase of another 31 million treatments courses. Thus, additional money will be needed to meet our goal to have enough antivirals for 25 percent of the population during a pandemic. Congressional support of \$2.3 billion for the second year of the President's Pandemic Influenza plan will be critical to meet this goal.

The cornerstone of the HHS Pandemic Influenza Plan is to create domestic manufacturing capacity sufficient to produce 300 million vaccine courses within 6 months of the onset of a pandemic outbreak, and to maintain a stockpile of pre-pandemic vaccine. We currently have approximately 4 million courses of pre-pandemic vaccine against a clade 1 H5N1 avian influenza strain. Plans and procedures are also underway to manufacture pre-pandemic vaccine against a clade 2 H5N1 avian influenza strain that is currently circulating the globe.

On May 4, 2006 Secretary Leavitt announced the award of \$1 billion for five contracts to support the development of advanced techniques using a new cell-based, rather than an egg-based, approach to producing influenza vaccines. Using a cell culture approach to producing influenza vaccine is a promising technology and offers a number of benefits. Vaccine manufacturers can bypass the step needed to adapt the virus strains to grow in eggs. In addition, cell culture-based influenza vaccines will help meet surge capacity needs in the event of a shortage or pandemic, since cells may be frozen in advance and large volumes grown quickly. U.S. licensure and manufacture of influenza vaccines produced in cell culture also will provide security against risks associated with egg-based production, such as the potential for egg supplies to be contaminated by various poultry-based diseases, including pandemic influenza strains. Finally, the new cell-based influenza vaccines will provide an option for people who are allergic to eggs and therefore unable to receive the currently licensed vaccines.

A total of \$1.7 billion in FY 2006 funding is allocated for vaccine development to increase vaccine production capacity by accelerating cell-based manufacturing technology, increasing egg-based vaccine production capacity, and supporting the advanced development for antigen sparing technologies that could extend the vaccine supply by decreasing the amount of antigen needed to protect each individual.

Progress has also been made in the SNS purchase of medical supplies and equipment essential to pandemic readiness. HHS has purchased over 150 million N95 respirators and surgical masks with approximately \$50 million of FY06 funds. Other planned

procurements include personal protective equipment (PPE), ventilators, IV antibiotics, and other medical supplies. Advanced development for rapid diagnostic tests also continues through the use of FY06 funds. A request for information (RFI) was issued for a point-of-care diagnostic on March 30, 2006 and a request for proposal (RFP) will be issued soon.

State and Local Preparedness

Pandemic influenza preparedness requires the active planning and participation of States and local communities. If a pandemic were to occur in the U.S., it would likely affect thousands of communities at the same time over the course of many weeks. The Federal Government is working to provide guidance regarding how state, local, and tribal governments can develop pandemic preparedness plans and respond in the event of a pandemic. As part of the Administration's effort to enhance State and local pandemic preparedness, HHS has held pandemic influenza summits in 47 States and the District of Columbia so far. These summits have brought together State and local officials, public health, schools, businesses, and other stakeholders to discuss pandemic preparedness. With the FY 2006 emergency funding, HHS has awarded \$100 million of the \$350 million allocated for State preparedness for pandemic influenza preparedness planning activities. The remaining portion of these funds will be awarded based on benchmarks that will measure States' progress.

It is important to note that HHS funding to enhance State and local preparedness for public health emergencies, including pandemic influenza, has existed since 2001.

Principally through CDC and HRSA funds have been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and state health departments to enhance disease reporting.

First, CDC provides preparedness funding annually to public health departments of all the States, certain major metropolitan areas, and other eligible entities through cooperative agreements. Second, HRSA employs complementary cooperative agreements to provide preparedness funding annually within States for investment primarily in hospitals and other healthcare entities. HHS collaborates with DHS toward ensuring that the guidance associated with the CDC and HRSA awards is coordinated with the guidance associated with those DHS awards that address other aspects of State and local preparedness, such as emergency management and law enforcement. Including the funding we have requested for FY07, CDC and HRSA's total investments in State and local preparedness since 2001 will total almost \$8 billion.

In addition, the ability to quickly increase the number of health care workers available is a critical component of State and local public health emergency response capacity. HRSA has supported efforts to improve personnel surge capacity. Funds are used to allow jurisdictions to develop or enhance Emergency Systems for Advance Registration of

Volunteer Health Professionals (ESAR-VHP), authorized under the Public Health Security and Bioterrorism Preparedness and Response Act. ESAR-VHP is designed to help States develop registries of volunteer health professionals whose credentials have been verified in advance of an emergency so that they can be quickly called on and utilized in an emergency. In addition to the FY07 budget request of \$8 million to continue HRSA's registration system, the budget also proposes development of a web-based portal that would create the means for integrating the state ESAR-VHP systems into a National system, thereby promoting a more coordinated national deployment of personnel. The portal is intended to not only integrate existing state ESAR-VHP systems, but to also provide a credentialing service that could assist states with the development of their ESAR-VHP databases. The budget also proposes to fund a Mass Casualty Initiative, including the Medical Reserve Corps and Healthcare Provider Credentialing and the Commissioned Corps Transformation initiatives.

Lastly, effective communications and outreach are essential to pandemic preparedness at the Federal, State and local levels. President Bush called for the development of a single, comprehensive web site to be the official Federal source of pandemic and avian influenza information. This web site, www.PandemicFlu.gov, includes a wide range of information on pandemic influenza and preparedness activities. In addition, HHS has developed a series of checklists intended to aid preparation for a pandemic in a coordinated and consistent manner across all segments of society. Thus far, ten checklists have been released and are aimed at State and local governments, the business community, the

education sector, the health sector, community organizations, and individuals and families.

Conclusion

Thank you for the opportunity to share this information with you. Although much has been accomplished, continued vigilance and preparation are needed for us to be ready for a pandemic. I am happy to answer any questions at this time.